MED-EL

Declaration of Conformity

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a
6020 Innsbruck, Austria

as manufacturer, declares under its sole responsibility that the

Mi1200 SYNCHRONY (PIN) COCHLEAR IMPLANT
AUDITORY BRAINSTEM IMPLANT AND THEIR ACCESSORIES

consisting of the following Active Implantable Medical Devices (AIMD)

Cochlear Implant Mi1200 SYNCHRONY with the following electrode variants:	
• Mi1200 SYNCHRONY PIN +Standard	09396
• Mi1200 SYNCHRONY + Standard	09395
• Mi1200 SYNCHRONY PIN + Compressed	09397
• Mi1200 SYNCHRONY + Compressed	09408
• Mi1200 SYNCHRONY PIN + Medium	09399
• Mi1200 SYNCHRONY + Medium	09398
• Mi1200 SYNCHRONY PIN +FLEX^{24}	09401
• Mi1200 SYNCHRONY +FLEX^{24}	09400
• Mi1200 SYNCHRONY PIN + FLEX^{SOFT}	09403
• Mi1200 SYNCHRONY + FLEX^{SOFT}	09402
• Mi1200 SYNCHRONY + PIN FLEX^{28}	09405
• Mi1200 SYNCHRONY + FLEX^{28}	09404
• Mi1200 SYNCHRONY PIN + FORM^{19}	30893
• Mi1200 SYNCHRONY + FORM^{19}	30892
• Mi1200 SYNCHRONY PIN + FORM^{24}	30895
• Mi1200 SYNCHRONY + FORM^{24}	30894
• Mi1200 SYNCHRONY PIN+ FLEX^{20W}	30897
• Mi1200 SYNCHRONY + FLEX^{20W}	30896
• Mi1200 SYNCHRONY PIN + FLEX^{20}	07882
• Mi1200 SYNCHRONY + FLEX^{20}	07880
• Mi1200 SYNCHRONY PIN + FLEX^{26}	36618
• Mi1200 SYNCHRONY + FLEX^{26}	36617
EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)	

Auditory Brainstem Implant Mi1200 SYNCHRONY in the following variants:	
• Mi1200 SYNCHRONY PIN ABI	09407
• Mi1200 SYNCHRONY ABI	09406
EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)	

Mi1200 Implant Template in the following variants:	
Mi1200 Implant Template PIN	09800
Mi1200 Implant Template	09799
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fulfill the essential requirements of the Directive 90/385/EEC on Active Implantable Medical Devices (AIMD).

Digitally signed by Timus Andrei
Date: 2021.06.08 21:06:30 EEST
Reason: MoldSign Signature
Location: Moldova

MED-EL has implemented a quality assurance system for design, manufacture and final inspection of the above products according to Annex 2, section 3 of the Directive. This quality assurance system conforms to the provisions of the Directive.
A Design Examination on the above products has been carried out by the Notified Body according to Annex 2, section 4 of the Directive 90/385/EEC on Active Implantable Medical Devices. The design of the above devices conforms to the provisions of this Directive.

The devices are designed and manufactured in compliance with the following standards:
EN ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016.

Innsbruck, August 04, 2020
(Place and date of issue)

(Dr. Ingeborg Hochmair, CEO)

(Elizabeth Gfoeller, Corporate Director, Regulatory Affairs)

(Martin Herzog, Corporate Director, Quality Assurance)

EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)
EC Full Quality Assurance Certificate Number: No. I1 017853 0127 Rev. 01 (Valid until: 26-05-2024)
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany.
Notified Body Identification Number: 0123